

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
KRAMER et al.) Applications
)
Serial No. Not Assigned)
)
Filed:)
)
For: USE OF LIPOIC ACID FOR IMPROVING THE BIOAVAILABILITY
OF MINERAL SALTS

PRELIMINARY AMENDMENT

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

Prior to examination, kindly amend the above-identified application as follows.

IN THE CLAIMS

Please amend the claims as shown in the attached sheets.


REMARKS

The claims have been amended to eliminate multiple dependency. No new matter has been added. A clean copy of the claims is attached.

Entry of the above amendment is respectfully solicited.

Respectfully submitted,

KEIL & WEINKAUF


Herbert B. Keil
Reg. No. 18,967

1101 Connecticut Ave., N.W.
Washington, D.C. 20036
(202)659-0100

CLEAN VERSION OF AMENDED CLAIMS - OZ 51568

4. The use as claimed in claim 1, wherein the combination used is metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes.
6. The use as claimed in claim 1, wherein the α -lipoic acid used is (R)- α -lipoic acid or the α -lipoate used is (R)- α -lipoate.
15. The use of the metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 for treating diabetes, tumors, HIV infections, AIDS, renal insufficiency, malnutrition, protein-energy malnutrition and mineral deficiencies.

109020-2262680

MARKED UP VERSION OF AMENDED CLAIMS

4. The use as claimed in claim 1 [or 2], wherein the combination used is metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes.
6. The use as claimed in claim 1 [one of claims 1 to 5], wherein the α -lipoic acid used is (R)- α -lipoic acid or the α -lipoate used is (R)- α -lipoate.
15. The use of the metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 [in accordance with claim 14] for treating diabetes, tumors, HIV infections, AIDS, renal insufficiency, malnutrition, protein-energy malnutrition and mineral deficiencies.

105020-22646990

CURRENT CLAIMS - CLEAN COPY - OZ 51568

1. The use of α -lipoic acid or α -dihydrolipoic acid for increasing the bioavailability of mineral salts.
2. The use as claimed in claim 1, wherein at least one mineral salt is used in combination with α -lipoic acid or α -dihydrolipoic acid.
3. The use as claimed in claim 2, wherein mineral salts of the formula I are used,



where

M is a monovalent to trivalent physiologically acceptable metal cation,

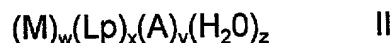
B is a monovalent to trivalent physiologically acceptable anion,

n is 1, 2 or 3 and

m is 1, 2 or 3,

where the subscripts n and m correspond to the valency and charge equalization of the mineral salt of the formula I.

4. The use as claimed in claim 1, wherein the combination used is metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes.
5. The use as claimed in claim 4, wherein the combination used is metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes of the formula II,



where

M is a monovalent to trivalent physiologically acceptable metal cation or a mixture of monovalent to trivalent physiologically acceptable metal cations,

Lp is racemic α -lipoic acid or α -dihydrolipoic acid, (R)- or (S)- α -lipoic acid or (R)- or

CURRENT CLAIMS - CLEAN COPY - OZ 51568

(S)- α -dihydrolipoic acid, racemic α -lipoate or dihydro- α -lipoate or (R)- or (S)- α -lipoate or (R)- or (S)-dihydro- α -lipoate,

A is a physiologically acceptable monovalent or divalent anion,

w is 1 or 2

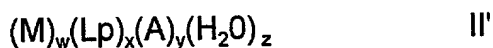
x is 1, 2, 3 or 4,

y is 0, 1, 2 or 3 and

z is 0, 1, 2, 3, 4, 5, or 6,

where the subscripts w, x and y correspond to the valency and charge equalization of the compound of the formula II.

6. The use as claimed in claim 1, wherein the α -lipoic acid used is (R)- α -lipoic acid or the α -lipoate used is (R)- α -lipoate.
7. A preparation comprising at least one mineral salt and (R)- α -lipoic acid or (S)- α -lipoic acid.
8. A metal α -lipoate, metal α -dihydrolipoate or metal- α -lipoic acid complex of the formula II',



where

M is a monovalent to trivalent physiologically acceptable metal cation or a mixture of monovalent to trivalent physiologically acceptable metal cations,

Lp is racemic α -lipoic acid or α -dihydrolipoic acid, (R)- or (S)- α -lipoic acid or (R)- or (S)- α -dihydrolipoic acid, racemic α -lipoate or dihydro- α -lipoate or (R)- or (S)- α -

CURRENT CLAIMS - CLEAN COPY - OZ 51568

lipoate or (R)- or (S)-dihydro- α -lipoate,

A is a physiologically acceptable monovalent or divalent anion,

w is 1 or 2,

x is 1, 2, 3 or 4,

y is 0, 1, 2 or 3 and

z is 0, 1, 2, 3, 4, 5 or 6,

where the subscripts w, x and y correspond to the valency and charge

equalization and

the following compounds are excluded:

$\text{Mn}(\text{lip}^-)\text{ClO}_4$, $\text{Cu}(\text{Lip}^-)\text{ClO}_4$, $\text{Zn}(\text{Lip}^-)\text{ClO}_4$, $\text{Cd}(\text{Lip}^-)\text{ClO}_4$, $\text{Pb}(\text{Lip}^-)\text{ClO}_4$, $\text{Hg}(\text{Lip}_{\text{rac}})(\text{OH})_2$,

$\text{Hg}(\text{DHL}_{\text{rac}}^{2-})$, $\text{Ni}(\text{DHL}_{\text{rac}}^{2-})$, $\text{Fe}_2(\text{DHL}_{\text{rac}}^{2-})_3$, $\text{Zn}(\text{Lip}_{\text{rac}}^-)_2(\text{H}_2\text{O})_2$, $\text{Cd}(\text{Lip}_{\text{rac}}^-)_2(\text{H}_2\text{O})_2$

where

Lip^- is monovalent negative racemic or (R)- or (S)- α -lipoate,

$\text{Lip}_{\text{rac}}^-$ is monovalent negative racemic α -lipoate,

Lip_{rac} is racemic α -lipoic acid and

$\text{DHL}_{\text{rac}}^{2-}$ is divalent negative racemic α -dihydrolipoate.

9. A preparation comprising metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 8.
10. A preparation comprising metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 and α -lipoic acid or α -dihydrolipoic acid.

CURRENT CLAIMS - CLEAN COPY - OZ 51568

11. The use of the metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 as feedstuff or food supplements.
12. The use of the metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 in cosmetic formulations!
13. The metal α -lipoate, metal α -dihydrolipoate or metal- α -lipoic acid complex as claimed in claim 5 for use as drugs.
14. The use of metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 for preparing a drug for treating disorders in which lipoic acid has a therapeutic or prophylactic effect and there is a mineral salt deficiency.
15. The use of the metal α -lipoates, metal α -dihydrolipoates or metal- α -lipoic acid complexes as claimed in claim 5 for treating diabetes, tumors, HIV infections, AIDS, renal insufficiency, malnutrition, protein-energy malnutrition and mineral deficiencies.